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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room1061
Rockville, MD 20852

To: Nancy Myers
Re: FDA Critical Path Project and Epilepsy. Docket ID # 2004-N-0181
From: Susan Axelrod, President, CURE

Over one-third of the 2.3 million epilepsy patients in the United States continue to have seizures despite using current therapies. Many others must tolerate serious side effects, including diminished cognition, as a price for seizure control. The risk of sudden death for those with intractable epilepsy is significantly higher than it is for those without.

New therapies introduced in the last decade offer fewer side effects but have done little to bring seizure control to the many patients living with active and uncontrolled epilepsy. This may be because we still have not found that 'magic bullet', and it may also be because newer therapies are not finding their way to the patients who could potentially benefit from them. Under the care of general neurologists and family physicians, many of these patients continue to be treated with the older, more familiar epilepsy treatments.

Despite the obvious need, funding for epilepsy research in both the public and private sectors is well below where it should be given the number of patients impacted.

As the parent of a 23 year old daughter who has suffered from intractable epilepsy since the age of 7 months, I am acutely aware of these funding issues and also the hurdles for the pharmaceutical industry in developing and bringing to market new epilepsy treatments.

Mostly, though, I am painfully aware of the human cost of epilepsy—the devastation that befalls people whose epilepsy cannot be controlled. And, the need to expedite the transmission of research discoveries to those patients in need.

My daughter, Lauren, began to have seizures out of the blue for no apparent reason at the age of 7 months. Over the next 18 years, we watched as over 20 different medications in varied combinations failed to control her seizures. We continued to lose hope as other

potential treatments—the ketogenic diet, vagal nerve stimulation and surgery were equally unsuccessful.

And we despaired as we watched our previously healthy, normally developing baby lose developmental ground. We were terrified as we watched thousands of seizures, some potentially life-threatening, rob her of her childhood, her well-being and her potential.

Over four years ago, on the day that a new anticonvulsant came onto the market, it was added to Lauren's regimen (since the first drug failed, Lauren has never been on less than three medications at a time, which for obvious reasons only serves to complicate her treatment).

Since that day, in April of 2000, she has not had a single seizure.

The odds of that happening were extraordinarily slim. We don't understand why, after all the previous efforts, this particular medication worked. She still continues to take a daily 'cocktail' of 4 medications, though we have been able to reduce some dosages and thereby reduce side effects.

The brain damage from repeated, uncontrolled seizures will be with her for life. She requires 24 hour a day support. But, the improvement in her life, her outlook, her cognition and just her ability to live are beyond description. She is doing remarkably well--in fact it is nothing short of a miracle.

By elevating epilepsy to a disease to receive your attention in the Critical Path Project, you have the potential to bring similar miracles to other patients whose lives are being destroyed. Intractable epilepsy is a serious, debilitating public health problem with effects that last a lifetime.

I don't pretend to fully understand the issues surrounding the workings of the FDA and the pharmaceutical industry. But, I am writing at this time because I understand this may be a long overdue opportunity to look at epilepsy treatment and clinical trials in a new light. To expedite bringing epilepsy treatments to those whose lives are being destroyed. To encourage the development of more effective and kinder treatments and to ensure that patients can access them as first line treatment, thus decreasing side effects, and potentially the need for patients to be on multiple medication combinations. To render more patients seizure- and side effect- free, which is the ultimate goal of all of us in the epilepsy community.

Thank you for listening to my story. Sadly, unlike Lauren, far too many people with epilepsy continue to suffer. And they suffer quietly, as public awareness about epilepsy lags far behind that of other diseases. Your selection of epilepsy as a disease which merits priority, could go a long way toward elevating awareness and alleviating the devastation and destruction caused by uncontrollable seizures.

Thank you for your attention and your consideration.